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Special report

EU COVID-19 vaccine procurement

Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed

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Contents

Executive summary

I The EU identified vaccines as a priority in the response to COVID-19 early on in the pandemic, and started focusing on the development of a safe and efficient vaccine as a solution to ending the health crisis. It took measures to help compress the development timeline for vaccines from 10-15 years to 12-24 months. By November 2021, the Commission had signed €71 billion worth of contracts on behalf of the Member States to purchase up to 4.6 billion COVID-19 vaccine doses. Most of these contracts are advance purchase agreements, in which the Commission shares the development risk of a vaccine with the vaccine manufacturers and supports the preparation of at-scale production capacity through upfront payments from the EU budget.

II The EU experienced some supply shortfalls in the first half of 2021, but by the end of that year, nearly 952 million vaccine doses had been delivered to EU Member States and 80 % of the EU's adult population had been fully vaccinated.

III This report examines whether the Commission and Member States procured COVID-19 vaccines up to the end of 2021 effectively. We looked at the framework the EU set up, its negotiation strategy and how the Commission followed up contract implementation. We chose this topic given the central role that vaccines played in the response to the COVID-19 pandemic, the unprecedented nature of the EU's involvement in vaccine procurement and the expenditure involved. Our findings aim to contribute to the ongoing development of the EU's pandemic preparedness and response capabilities.

IV We found that the EU created a tailor-made centralised system for vaccine procurement, which succeeded in creating an initial portfolio of vaccine candidates including different companies and technologies, but it started procurement later than the UK and the US. The EU had to act ahead of clear scientific data on vaccine candidates' safety and efficacy, and therefore chose to back a range of candidates to create an initial portfolio with a range of different vaccine technologies and manufacturers. The Pfizer/BioNTech vaccine dominates the portfolio in 2022-2023 because of, according to the Commission, the company's ability to reliably supply the EU.

V Negotiations followed a procurement process laid down in the EU's Financial Regulation, while the heart of the process were the preliminary negotiations that took place before a tender invitation was sent out. The EU's negotiators were better able to

secure the EU's procurement objectives in the later contracts it signed with vaccine manufacturers. The terms of the contracts evolved over time and those signed in 2021 have stronger provisions on key issues such as delivery schedules and production location than those signed in 2020. The terms negotiated are different for each contract, except for adherence to the principles of the Product Liability Directive which regulates third party liability for adverse effects.

VI After contract signature, the Commission supported contract implementation by acting as a facilitator between the Member States and the manufacturers. However, the Commission had limited leverage to overcome supply challenges. When the EU was confronted with severe supply shortfalls in the first half of 2021, it became clear that most contracts did not include specific provisions to address supply disruptions. As such, the Commission could, and in one case did, take manufacturers to court. The Commission had also not fully analysed the production and supply chain challenges of vaccine production until after signing most of the contracts. The Commission only set up a task force to support manufacturing and supply chains in February 2021 and while it did help resolve bottlenecks, the size of its impact on the ramp-up of vaccine production was unclear.

VII The Commission has not yet scrutinised or benchmarked its procurement process to learn lessons for future improvements, nor does it currently plan to test its pandemic procurement system through stress-tests or simulations.

VIII Based on our findings, we recommend that the Commission:

- produce pandemic procurement guidelines and/or lessons learnt for future negotiating teams;
- carry out a risk assessment of the EU's procurement approach and propose appropriate measures;
- run exercises to test all parts of its updated pandemic procurement framework, including information and intelligence gathering, to identify any weaknesses and areas for improvement and publish the results.

Introduction

01 The World Health Organisation (WHO) declared the COVID-19 outbreak a global pandemic on 11 March 2020[1]. The Joint (European Council and Commission Presidents') European Roadmap towards lifting COVID-19 containment measures of 26 March 2020 stressed that "the development of a safe and effective vaccine is crucial to help put an end to the COVID-19 pandemic"[2]. The Commission published its COVID-19 vaccines strategy on 17 June 2020, presenting the rationale for a centralised EU procurement process. The Commission argued that a centralised approach "allows better hedging of bets, sharing of risks and pooling investments to achieve economies of scale, scope and speed"[3]. The strategy rests on two pillars:

- securing sufficient production of vaccines in the EU and thereby sufficient supplies for its Member States; and
- adapting the EU's regulatory framework to the current urgency and making use of existing regulatory flexibility.

The development of COVID-19 vaccines

02 Developing a successful vaccine takes an average of 10 to 15 years[4] (see ***Figure 1***). When the EU's procurement process started in mid-2020, it was not known if or when a COVID-19 vaccine would reach the market. The Commission therefore supported different vaccine candidates and technologies to promote a fast response from the market and spread the risk of failure and delay.

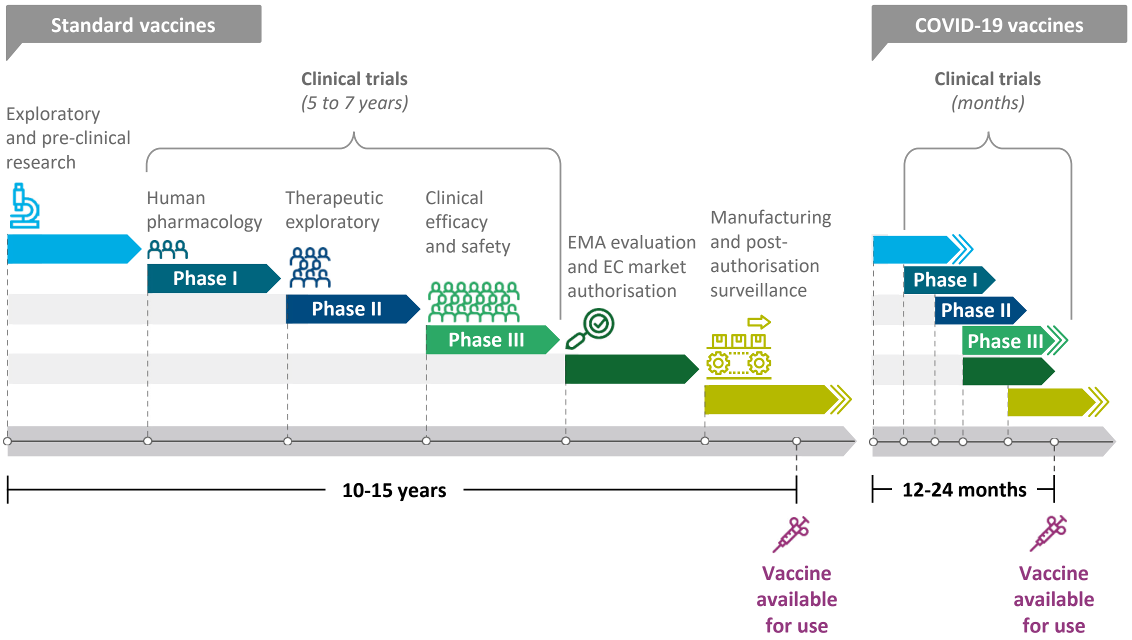
1 WHO Director-General's opening remarks at the media briefing on COVID-19, 11.3.2020.

2 Joint European Roadmap towards lifting COVID-19 containment measures, 26.3.2020.

3 EU strategy for COVID-19 vaccines, COM(2020) 245.

4 International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), "The complex journey of a vaccine. The steps behind developing a new vaccine".

Figure 1 – Standard vaccine development process and timeline vs COVID-19 vaccine development



Source: ECA, based on EMA and IFPMA information.

03 The EU took a number of measures to support efforts to compress the COVID-19 vaccine development timeline to as little as 12-24 months[5] (see ***Figure 1***). The European Medicines Agency (EMA) provided rapid guidance to developers on clinical study designs, advised companies on regulatory requirements, undertook rolling reviews of clinical trial data as it became available and sped up the approval of new production lines[6]. The Council and the European Parliament adopted a temporary derogation from the legislation on genetically modified organisms, allowing their inclusion in vaccines[7]. The heads of the Member States' Medicines Agencies adopted a Memorandum of Understanding allowing more flexible labelling and packaging requirements for COVID-19 vaccines. The EMA recommended granting conditional marketing authorisation for the first COVID-19 vaccine on 21 December 2020, nine months after the WHO had declared the coronavirus outbreak a global pandemic.

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[5] EU strategy for COVID-19 vaccines, COM(2020) 245.

[6] EMA, "COVID-19 vaccines: development, evaluation, approval and monitoring".

[7] Regulation (EU) 2020/1043.

Contracts to procure COVID-19 vaccines

04 In parallel with the publication of its COVID-19 vaccine strategy, the Commission signed an agreement with the 27 Member States, allowing it to conclude Advance Purchase Agreements (APAs) with COVID-19 vaccine manufacturers on their behalf[8]. APAs are contracts in which the Commission secures Member States' right to buy a specified number of vaccine doses in a given timeframe and at a given price. In return for securing future vaccine supplies, part of the development costs faced by vaccine producers was financed by down payments from the EU budget. The Commission and Member States took this novel risk-sharing approach to secure sufficient quantities of vaccines. If the EMA recommends a vaccine for authorisation, the down payments are used against purchases of the vaccine by the Member States. However, these payments may not always be fully recovered in the event that a vaccine candidate is not authorised.

05 Funding for the APAs came from the Emergency Support Instrument (ESI)[9], a financing instrument directly managed by the Commission that allows it to provide support within the EU in case of disasters. It is used to intervene on top of, and in coordination with, efforts made under other national and EU initiatives. The Commission allocated €2.15 billion to the ESI budget to fund vaccine APAs, which the Member States topped up with a further €750 million to create a total budget of €2.9 billion. By the end of 2021, the Commission had paid more than €2.55 billion in down payments to vaccine manufacturers.

The Commission signed contracts worth €71 billion for deliveries of up to 4.6 billion COVID-19 vaccine doses

06 Between August 2020 and November 2021, the Commission signed 11 contracts with eight vaccine manufacturers providing access to up to 4.6 billion vaccine doses (see ***Table 1***) at an expected total cost of close to €71 billion. The weighted average cost per dose is approximately €15. This figure is calculated on the basis of doses actually ordered (delivered and yet to be delivered). Options not exercised are not included. The Curevac doses ordered are excluded, but the Curevac down payment is included as a cost.

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[8] Commission Decision of 18 June 2020, C(2020) 4192 and its subsequent approval by each Member State.

[9] EU strategy for COVID-19 vaccines, COM(2020) 245.

Table 1 – Potential COVID-19 vaccine doses secured up to the end of 2021

Vaccine developed by	Number of contracted doses (million)	Number of optional/ additional doses (million)	Total number of doses (million)	Contract signature
AstraZeneca	300	100	400	August 2020
Sanofi/GSK		300*	300	September 2020
Janssen**	200	200	400	October 2020
Curevac	225	180	405	November 2020
Pfizer/BioNTech	200	100	300	November 2020
	200	100	300	February 2021
	900	900	1 800	May 2021
Moderna	80	80	160	December 2020
	150	150	300	February 2021
Novavax	100	100	200	August 2021
Valneva	24	36	60	November 2021
Total	***2 379***	***2 246***	***4 625***	

* **The Sanofi/GSK contract is an options contract with no obligation on the MS to purchase any doses. Sanofi/GSK received a down payment.**

** **Janssen Pharmaceutica NV is an affiliate of Johnson & Johnson.**

Source: ECA based on contracts.

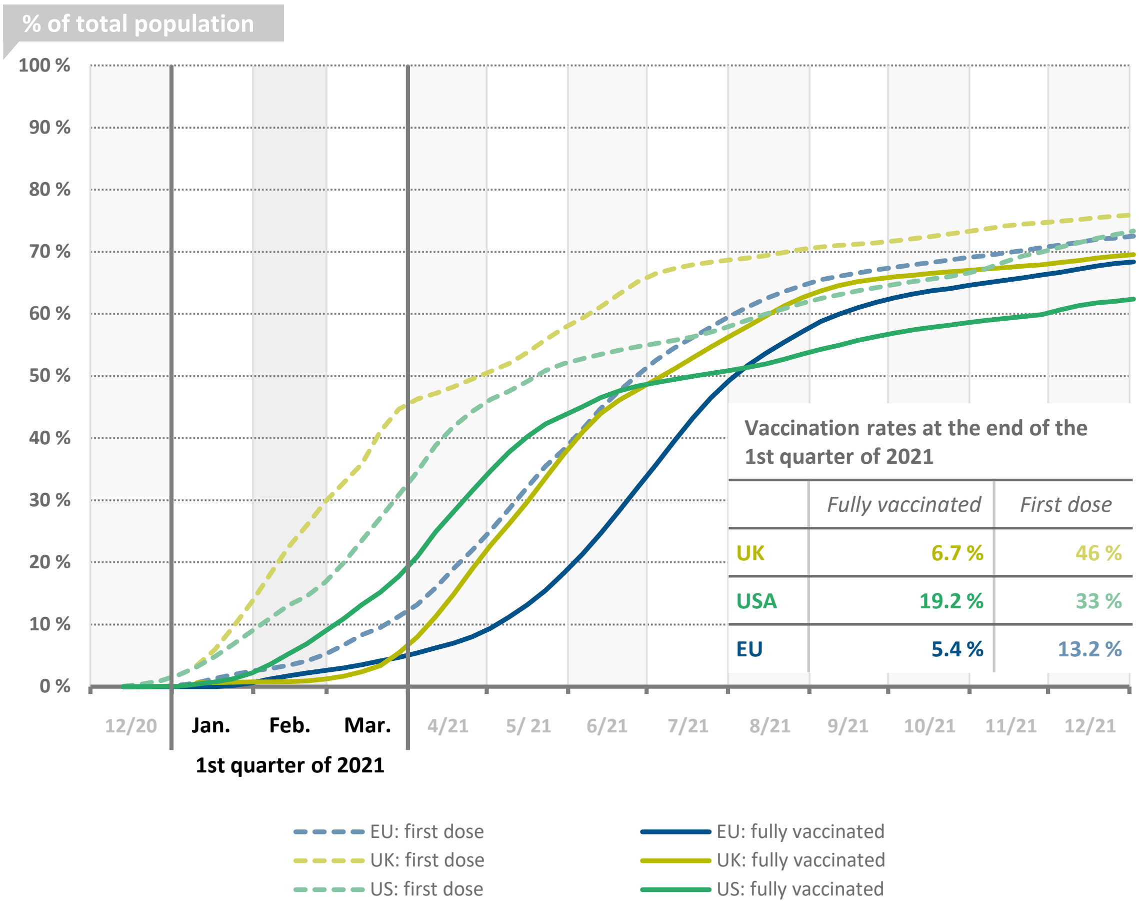
07 Eight of the contracts are APAs, concluded before the vaccines received a recommendation for a conditional marketing authorisation from the EMA. Three contracts are purchase agreements (PAs), signed with Pfizer/BioNTech and Moderna after their vaccines had received an EU conditional marketing authorisation. These do not include any down payment from the EU budget, though Moderna required a down payment from the Member States.

08 By the end of 2021, almost 952 million doses had been delivered to EU Member States (the majority from Pfizer/BioNTech) and over 739 million doses administered[10]. 80 % of the EU's adult population had been fully vaccinated. The EU had secured sufficient doses to vaccinate at least 70 % of the adult population by the end of the

[10] ECDC vaccine tracker.

summer of 2021 (see *Figure 2*), although it experienced challenging supply shortfalls from two manufacturers in the first half of 2021.

Figure 2 – Vaccination rates in the EU, UK and USA in 2021



Source: Our world in data for UK and USA, ECDC for the EU.

Liability and indemnification

09 The Commission and Member States considered early introduction of the vaccine to be in the interest of public health. Member States were therefore willing to reduce manufacturers' risks linked to liability for adverse effects. This was intended as a risk-sharing principle in the vaccine strategy. While respecting the general principle of liability under the Product Liability Directive (see *Box 1*), the provisions in the contracts concluded with COVID-19 vaccine manufacturers differ from the pre-pandemic practice (see *Box 1*) as Member States have taken over some of the financial risks normally assumed by the vaccine manufacturers.

Box 1

The EU Product Liability Directive

Under the Product Liability Directive, producers are liable for damage caused by a defect in their product, even in the absence of negligence or fault on their part. A producer can be exempt from such liability if the state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the defect to be discovered.

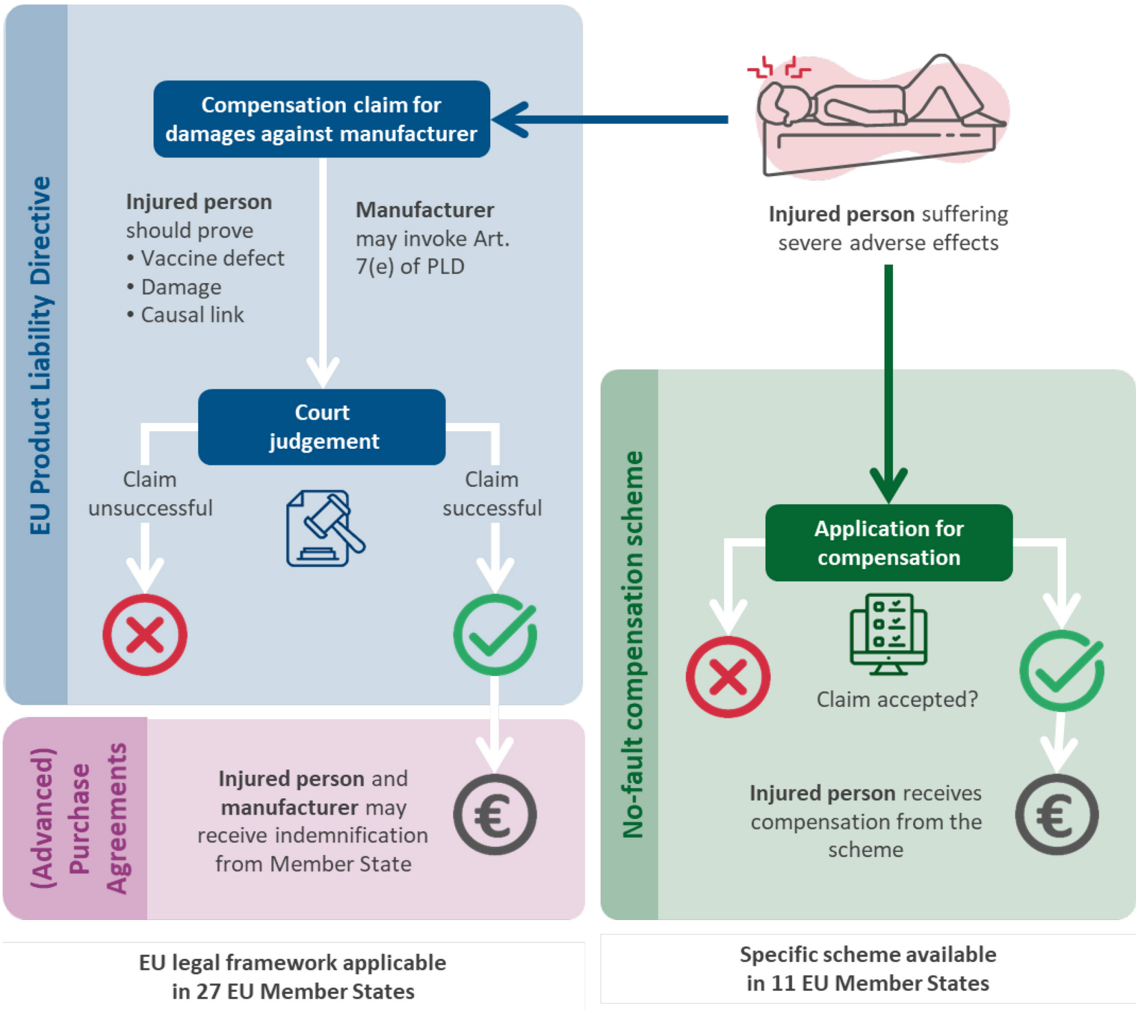
An EU citizen who suffers serious adverse effects from a medicine can file a compensation claim for damages against the manufacturer under the Directive, which has been enacted in Member States' legislation.

10 A citizen who has suffered adverse effects from one of the COVID-19 vaccines purchased under the contracts can claim damages against the manufacturer of the vaccine. If the claim is successful, the Member State that administered the vaccine will be responsible for compensating the injured party and paying the vaccine manufacturer's legal costs (indemnification) (see ***Figure 3***). This is not the case if the damages or losses result from wilful misconduct, gross negligence or failure to comply with EU good manufacturing practices.

11 In addition to claims under the Product Liability Directive, according to a recent study[11], 11 Member States have national "no fault" compensation schemes in place to indemnify injured persons for harm suffered as a result of side effects caused by a vaccination. Such schemes do not require the injured person to prove a causal link between the side effect and the vaccine. A person that chooses to receive such compensation foregoes the right to file a case against the pharmaceutical company.

[11] House of the Oireachtas, Library and Research Service, "Vaccine Injury Compensation Programmes: An Overview", 20.4.2021.

Figure 3 – Liability and indemnification in case a person suffers serious adverse effects from a COVID-19 vaccine



Source: ECA.

Audit scope and approach

12 This report examines whether the Commission and Member States procured COVID-19 vaccines up to the end of 2021 effectively. We looked at this topic because of the importance of timely access to vaccines in sufficient quantities in the EU's response to the COVID-19 pandemic as well as the expenditure at stake, and interest in the Commission's role. We examined whether:

(a) the EU's preparations for the procurement of COVID 19 vaccines were effective;

(b) the EU's negotiators were able to secure the EU's procurement objectives in the contracts it signed with vaccine manufacturers; and

(c) the Commission addressed any issues impacting the supply of vaccines.

13 We benchmarked the EU's performance with that of the UK and the US to understand what lessons could be learnt from a comparison with other procurement systems. We chose these countries as both have domestic pharmaceutical research and production capacity, were among the first countries to start vaccine procurement procedures and procured from some of the same companies as the EU. We took account of the differing competences for public health in the three jurisdictions and therefore limited our benchmarking to comparable factors: timing of procurement launch, contractual terms and support for production.

14 We held meetings with Commission officials from the Directorate General for Health and Food Safety (DG SANTE), the lead DG in this matter, and had direct access to their databases. We also had meetings with staff from the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), the Commission's legal service and the Secretariat General who had been involved in the procurement process. We had access to the relevant Commission documents, with the exception of those related to the President of the Commission's involvement in preliminary negotiations with Pfizer/BioNTech. We examined meeting minutes, internal Commission reports, email correspondence and the (A)PAs (hereafter known as contracts).

15 We held meetings with auditors from the UK and US supreme audit institutions to benefit from their work on their governments' COVID-19 vaccine procurement efforts. We interviewed the representatives of three Member States who had a leading role in the procurement process. We carried out a survey of the Member States' representatives on the COVID-19 vaccine procurement steering board to obtain their

opinion on the EU's vaccine procurement, to which 14 out of 27 Member States responded.

16 The results of this audit are relevant to the ongoing development of the EU's pandemic preparedness and response capacity, including the European Health Emergency Preparedness and Response Authority (HERA).

Observations

The EU created a tailor-made procurement system for COVID-19 vaccines

17 In response to the COVID-19 pandemic, the Commission took a number of steps to be able to procure vaccines for EU citizens. We assessed whether the EU set up an appropriate framework for this vaccine procurement process, leading to timely contract negotiations.

The EU identified vaccines as a priority in the response to COVID-19 early on, but started procurement later than the UK and the US

18 On 20 February 2020[12], less than three weeks after the WHO had declared COVID-19 a Public Health Emergency of International Concern[13], the Council urged Member States and the Commission to cooperate on the development of a vaccine (see ***Figure 4*** for a timeline of the key events). On 10 March[14] and again on 26 March 2020[15], the Members of the European Council stressed the importance of developing a vaccine and committed to increasing support for vaccine research.

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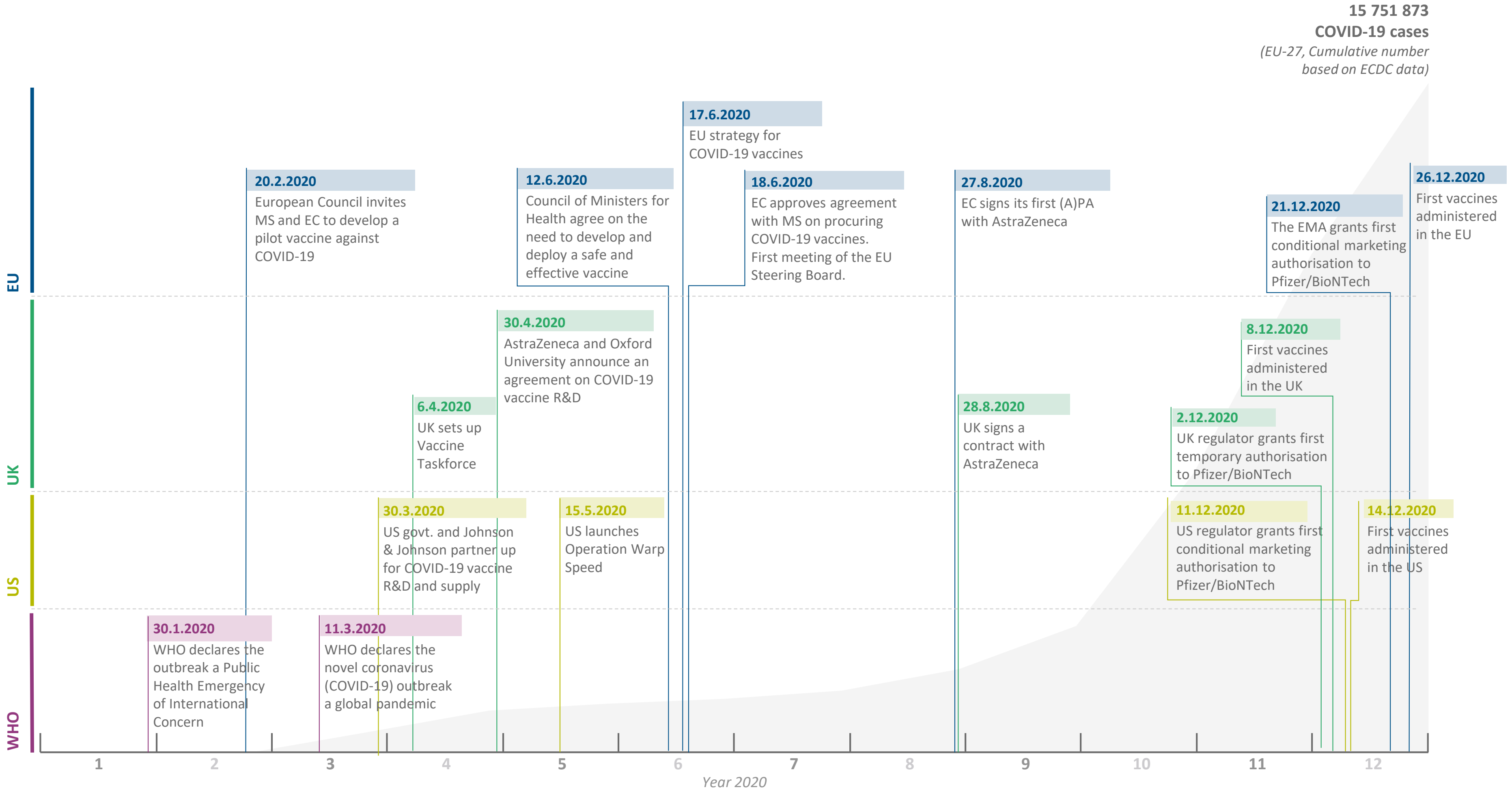
[12] Council conclusions on COVID-19 (2020/C 57/04).

[13] WHO, Statement regarding the outbreak of novel coronavirus, 30.1.2020.

[14] Conclusions by the President of the European Council, 10.3.2020.

[15] Joint statement of the Members of the European Council, 26.3.2020.

Figure 4 – Timeline of key COVID-19 procurement actions in 2020



Source: ECA.

19 On 17 April 2020, the joint Council-Commission roadmap towards lifting COVID-19 containment measures[16] stressed for the first time that joint procurement and equal access would guide the Commission's actions on vaccines. The Commission started investigating vaccine candidates in late April[17]. At this time, it did not have a mandate from the Member States, nor a final objective or strategy. It established these initial contacts without consulting or coordinating with the Member States.

20 Germany, France, Italy and the Netherlands had been working together as the Inclusive Vaccine Alliance (IVA) since May 2020 to secure vaccine supplies for their citizens. On 13 June, AstraZeneca announced a deal with the IVA for up to 400 million doses. Upon the launch of the EU's COVID-19 vaccine procurement on 18 June, the Commission and Member State negotiators took over the IVA agreement and negotiated with AstraZeneca on behalf of all 27 Member States.

21 The EU noted the importance of vaccine development early on in the pandemic, but started its procurement process (as measured by the establishment of the procurement steering board on 18 June 2020) later than the UK and USA. The UK launched its vaccine taskforce on 17 April 2020. The US government announced the creation of "Operation Warp Speed" for vaccine development and procurement on 15 May 2020, although it had started funding vaccine candidates' research in March (see ***Figure 4***).

[16] Joint European Roadmap towards lifting COVID-19 containment measures 2020/C 126/01.

[17] Ibid.

The EU set-up a novel centralised system to procure COVID-19 vaccines

22 The 2013 Decision[18] on serious cross-border threats to health provides an EU-level pandemic preparedness and response framework. The Commission has been supporting preparedness and response projects at EU and Member State level since 2003[19], in line with the WHO recommendations that such exercises (including at cross-border level) be an integral part of pandemic preparedness activities[20]. Nevertheless, the Council noted in April 2020 that "existing EU instruments are limited in scale and therefore do not allow a sufficient response or make it possible to address effectively the large-scale consequences of the COVID-19 crisis within the Union"[21]. These limitations included the absence of a system to procure an as yet non-existent vaccine:

- emergency support rules within the Union[22] did not allow the Commission to purchase supplies, such as vaccines, on behalf of Member States;
- the Decision[23] allows for the joint procurement of medical countermeasures by Member States, but this instrument was designed as a preparedness instrument and does not provide the flexibility and speed required to respond to the extreme urgency of the COVID-19 pandemic.

23 An April 2020 amendment to the Council Regulation on emergency support within the Union addressed these issues by allowing the Commission to negotiate contracts on behalf of the Member States for the first time. The Commission informed us that there was no vaccine strategy to implement this provision at the time the amendment was adopted.

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[18] Decision 1082/2013 on serious cross-border threats to health.

[19] European Commission website: "preparedness and response planning", accessed 22.2.2022.

[20] WHO, Recommendation for good practice in pandemic preparedness, 2010.

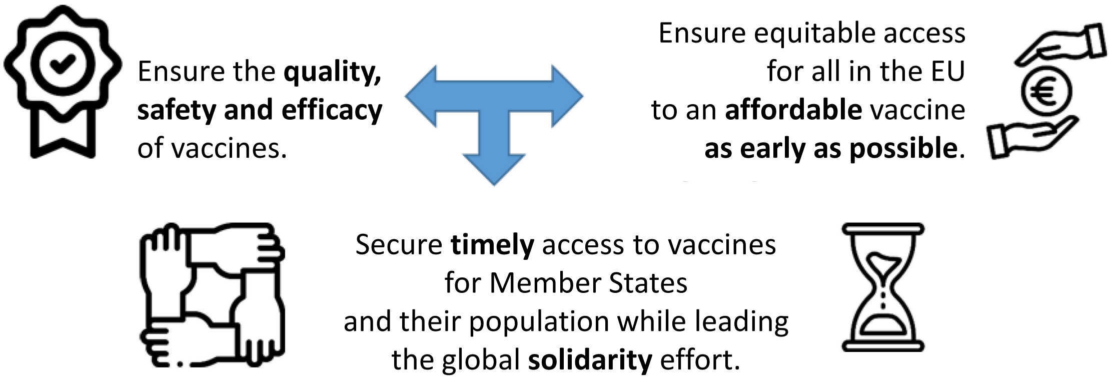
[21] Council Regulation (EU) 2020/521, recital 4.

[22] Council Regulation (EU) 2016/369 on the provision of emergency support within the Union.

[23] Article 5 of Decision 1082/2013 on serious cross-border threats to health.

24 The Council of Ministers for Health agreed on 12 June 2020[24] on "the need for joint action to support the development and deployment of a safe and effective vaccine against COVID-19 by securing rapid, sufficient and equitable supplies for Member States" and "favouring a broad portfolio and a top-up of ESI funding". The Commission published its COVID-19 vaccine strategy[25] on 17 June 2020 (see ***Figure 5***), presenting the rationale for a centralised EU procurement process. The Council adopted a financing decision on 18 June 2020 to fund vaccine procurement[26].

Figure 5 – The objectives of the EU COVID-19 strategy



Source: EU strategy for COVID-19 vaccines.

25 This centralised approach was implemented through an agreement signed by the Commission and the Member States, which made the Commission responsible for the procurement process and the conclusion of contracts. The agreements between the Commission and the Member States[27] set up a tailor-made system for the vaccine procurement (see ***Figure 6***), centred around two bodies:

- A steering board overseeing negotiations and validating contracts before signature, made up of one representative per Member State and co-chaired by the European Commission and a Member State representative. Representatives appointed to the steering board were not subject to any prerequisites or

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[24] Commission Decision approving the agreement with Member States on procuring Covid-19 vaccines, C(2020) 4192.

[25] EU strategy for COVID-19 vaccines, COM(2020) 245.

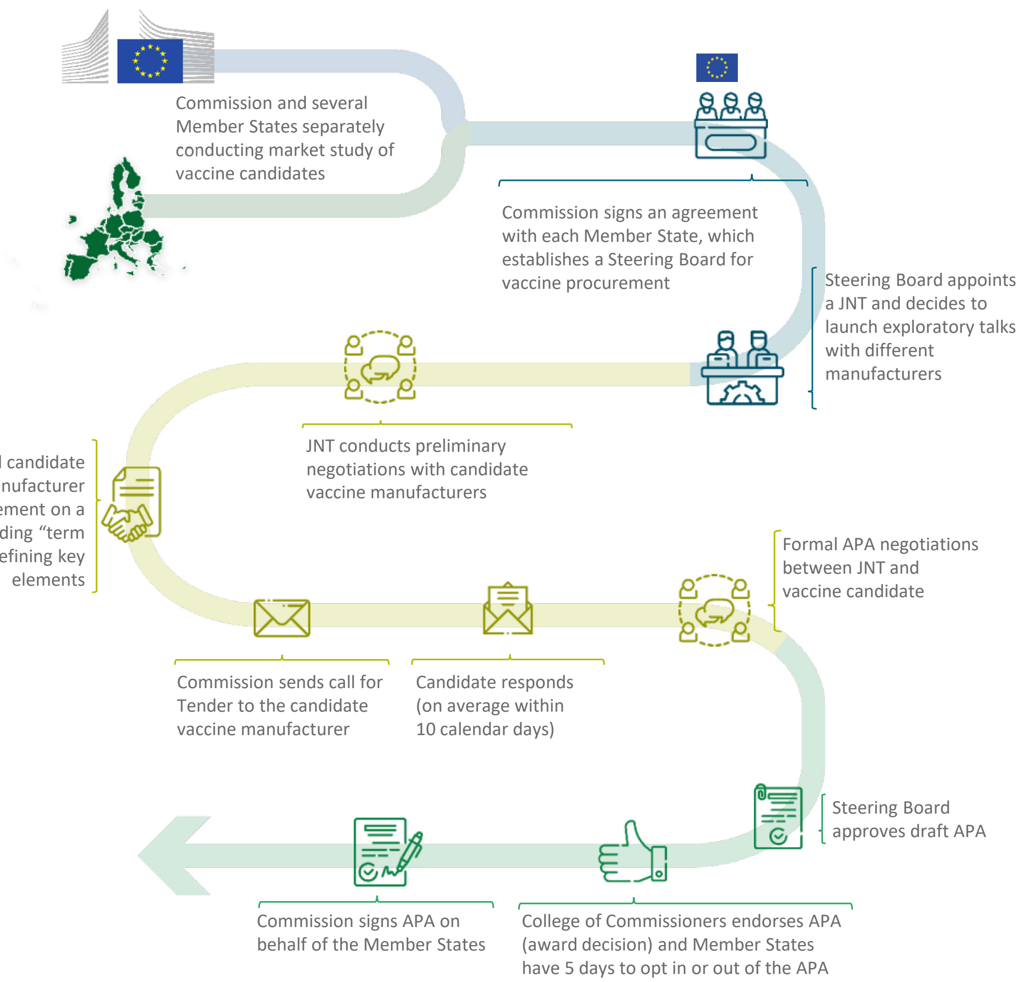
[26] Draft Amending Budget No 8 to the General Budget, C(2020) 900 final.

[27] Annex to the Commission Decision approving the agreement with Member States on procuring COVID-19 vaccines and its subsequent approval by each Member State.

requirements for specific expertise. This entailed the risk that the body overseeing vaccine procurement lacked the knowledge and experience to deal with the complexity of vaccine procurement.

- A joint negotiation team (JNT) in charge of negotiating the contracts, comprising representatives from seven Member States (Germany, Spain, France, Italy, the Netherlands, Poland and Sweden), chosen from the members of the steering board, and Commission officials from various DGs. In practice the JNT split into sub-groups of representatives from two Member States and Commission officials, each negotiating with a specific vaccine candidate manufacturer.

Figure 6 – Flowchart of the contract procurement process



Source: ECA.

26 The steering board and JNT were made up of people with a variety of profiles including members of the EMA Committee for Medicinal Products for Human Use and heads of Member States' national medicines agencies. The US and UK procurement taskforces included experts in supply chain and logistics. The Commission had not

considered which skills it needed in the JNT before the launch of the procurement process.

EU negotiators adopted a flexible approach to negotiations in the face of a high level of uncertainty

27 The Commission and Member States adopted a flexible approach to secure a broad vaccine portfolio at short notice, leaving the steering board to oversee the negotiations and validate their outcome. The steering board did not develop detailed objectives or mandates for the EU's negotiators. However, in its Decision approving the agreements with the Member States for vaccine procurement[28], the Commission did commit to considering specific elements when deciding to finance individual contracts, notably:

- available data on the quality, safety and efficacy of the vaccine at the time of negotiation of the contract;
- speed of delivery at scale;
- cost;
- diversification of technologies; and
- capacity to supply through the development of production capacity within the EU.

28 The JNT reported frequently to the steering board on the state of play of negotiations with the various vaccine candidates, but the steering board's meeting minutes make no mention of defined objectives or targets. They reflect the JNT's own assessment of the negotiations and record the steering board's occasional case-by-case instructions. The minutes rarely detail the matters the JNT was negotiating. The Commission informed us that, due to the urgency of the negotiations and the importance of avoiding leaks, these minutes do not exhaustively cover the discussions held within the steering board.

29 The steering board received input from Member States' experts on the scientific merit and potential of the various vaccine candidates. It chose to negotiate with established firms with track records in the field of vaccine development. The maturity of the vaccine candidates' technologies was also an important factor in the steering board's selection.

[28] Ibid.

30 The agreement between the Commission and Member States (see paragraph ***25***) stipulated that the Commission would seek independent scientific advice on both the progress and on the available data on the quality, safety and efficacy of vaccine candidates before making any final decisions. The Commission did ask scientific experts for advice but, in the absence of robust data, the steering board had to make decisions before clear scientific evidence was available.

Negotiations secured a diversified vaccine portfolio for Member States

31 Between spring 2020 and autumn 2021, the EU concluded 11 contracts with COVID-19 vaccine manufacturers. We assessed whether:

- the Commission mobilised the appropriate tools and knowledge to conduct the negotiations; and
- the contracts reflect the priorities and objectives defined for the negotiations.

The negotiations followed a three-step approach

32 The priorities of the COVID-19 vaccine procurement negotiations were to obtain a safe and effective vaccine quickly and in sufficient quantity for all EU Member States. The procurement process was conducted using a negotiated procedure without prior publication of a contract notice, in accordance with the Financial Regulation[29].

33 The negotiation process consisted of three stages, each of differing duration for each candidate manufacturer (see ***Figure 7***):

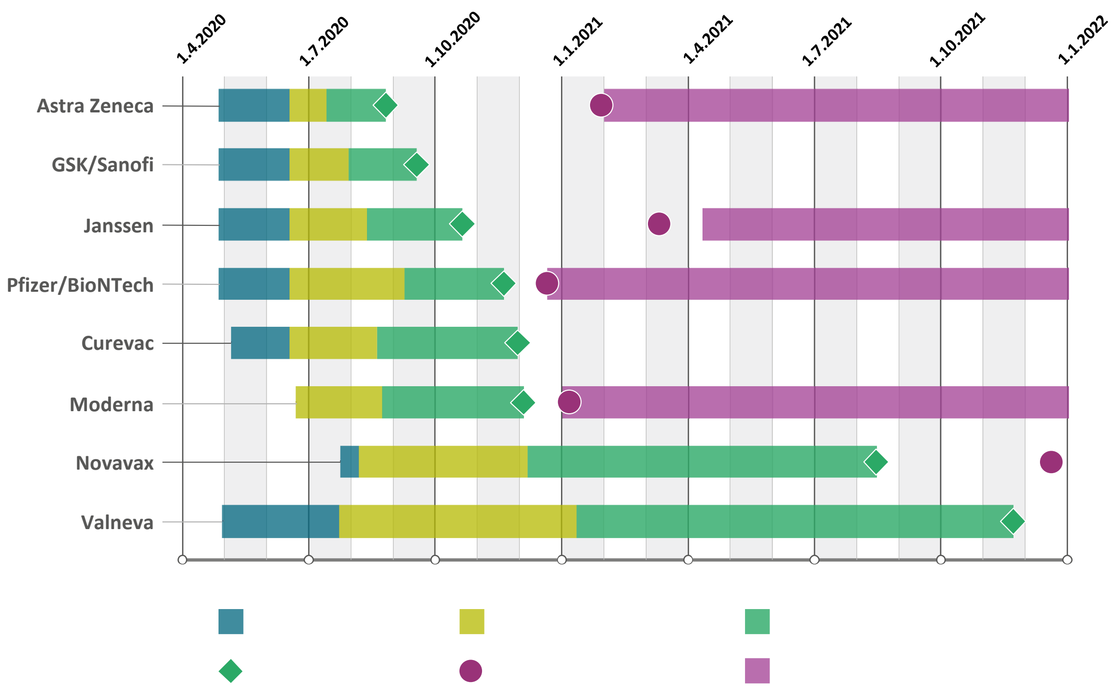
- *Market study*: the Commission sent questionnaires to candidate vaccine manufacturers and held meetings with some of them (this took place before the steering board was set up).
- *Preliminary negotiations* between the JNT and a candidate vaccine manufacturer started when the steering board gave its approval to start discussions and ended once the major elements of the agreement (price, volume, third party liability and indemnification, delivery and payment schedule) were provisionally agreed upon in non-binding "term sheets". When the steering board was satisfied with the

[29] Article 164(1)(d) and (4) and point 11(1)(c) of Annex I to Regulation 2018/1046.

outcome of the preliminary negotiations, the Commission could launch a call for tender.

- *Negotiations* between the JNT and a candidate vaccine manufacturer started when the company submitted a tender document and ended with the signature of an agreement by both parties (Commission, on behalf of the Member States, and manufacturer).

Figure 7 – Timeline of the negotiation process for each of the contracts



Source: ECA.

34 The EU followed a similar process to activate options for extra doses provided for in the contracts and to conclude two of the PAs. The steering board expressed interest in additional doses from a manufacturer and mandated the JNT to negotiate conditions.

Major elements were agreed in preliminary negotiations before the tender process

35 We analysed the tender process to determine its impact on the content of the contracts. An evaluation committee consisting of between five and 23 people from the Commission and the steering board produced evaluation reports on the files submitted by manufacturers in response to the call for tenders. We found that, for the first nine

contracts, the call for tenders did not add to what had been agreed informally on major elements in the term sheets.

36 Firstly, the vaccine candidate manufacturers and the JNT agreed major elements (notably price, volume and third party liability) of future contracts during the preliminary negotiations. Only then were the calls for tender launched. This is reflected in the short time between the tender invitation and the deadline for submitting tender documents (10 days).

37 Secondly, we found that one of the evaluation criteria was not updated to take account of the evolving situation. Criterion 1.1 "Roadmap towards starting clinical trials plans in 2020" was designed in mid-2020 to judge the reliability of candidates' plans to start clinical trials quickly. The tender invitations sent in December 2020 and January 2021 still included this criterion despite the fact that the evaluators were judging companies past performance rather than their expected output.

38 Thirdly, the evaluation of offers did not identify risks to the supply chain and manufacturing process that might lead to delivery problems. There is a weak correlation between the marks awarded and subsequent delivery performance. Approximately 40 % of the points that could be awarded to manufacturers under the tender were related directly to their production capacity (see ***Table 2***). All six companies that signed contracts with the Commission in 2020 received at least half marks for each criterion and four received maximum points for the criterion regarding production capacity in the EU.

Table 2 – Production-related criteria in the EU call for tenders for COVID-19 vaccines

The capacity to produce at scale the required volumes for the EU
Response capacity (to what extent and at what speed the company is capable of delivering proposed quantities)
Production capacity in the EU (linked to vaccines)

Source: EU calls for tenders for the development, production, priority-purchasing options and supply of COVID-19 vaccines for EU Member States.

39 Price, third party liability and delivery schedules were priority topics during the preliminary negotiations. The JNT did not assess companies' supply and production networks during preliminary negotiations and, despite the focus on this issue within the call for tender, it could not remedy this limitation in the short timeframe allowed

for tender evaluation. The Commission has recognised this weakness in the procurement process as it stated in February 2021 that manufacturers will have to submit "a detailed and credible plan showing capability to produce vaccines in the EU and deliver on a reliable timescale" as a prerequisite for negotiations[30].

Later contracts provided the EU with better guarantees for delivery and security of supply

40 We analysed the contracts with regard to: (i) enforcement of delivery schedules; (ii) guaranteeing EU access to the vaccines; (iii) the obligation to manufacture the vaccine in the EU; and (iv) respect for the EU's liability and indemnification legal framework. We found that the first three elements had weaker provisions in the early contracts.

Delivery schedules

41 Enforceable delivery schedules are one way to secure timely access to vaccines. However, the delivery schedules set out in most of the vaccine contracts are provisional and the parties acknowledge that delays may occur. Four of the 11 contracts explicitly state that the contractor is not liable for late deliveries. Five contracts mention the right to terminate the contract if any or all of the doses are not delivered by a fixed date or give the Commission the right to cancel orders if the delay exceeds a certain threshold. Four of the more recent contracts provide for discounts on the contractual price per dose for late deliveries.

42 According to the tender specifications the Commission sent to the manufacturers, the contracts may be terminated with contractors that do not have the capacity to produce a minimum number of doses as agreed in the contract. However, three of the contracts do not specify the condition for such termination, namely by when the contractor should have delivered the requisite number of doses.

EU access to vaccines

43 Another way to seek to secure timely supply of the vaccines is to ensure the order is prioritised and not overtaken by other orders. The UK negotiated provisions for priority access in four of its five contracts[31] (see ***Box 2***). Vaccine manufacturers in

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[30] Commission Communication on the HERA incubator, COM(2021) 78.

[31] UK National Audit Office, "Investigation into preparations for potential COVID-19 vaccines", 16.12.2020.

the US benefited from the government's ability to create "priority-rated contracts". This rating ensured that orders these manufacturers placed with their suppliers took precedence over those of any other clients (see ***Box 3***).

Box 2

The UK approach to vaccine procurement

The UK government established a vaccine taskforce in April 2020, bringing together up to 200 people from the civil service, army, industry and academia. Its objectives included securing access to COVID-19 vaccines and supporting the UK's industrial strategy to prepare for future pandemics[32]. In order to obtain a diversified portfolio of vaccine candidates at speed, administrative procedures, such as investment proposal and approval, were simplified.

The UK signed five APAs by November 2020, making down payments of £914 million in total[33]. Four of these APAs included priority delivery clauses and three contained provisions for partial or total reimbursement of upfront payments in case of failure. The terms of this priority delivery differ between contracts. For example, in one contract the priority supply is limited to the initial number of doses ordered. Another contract states that the UK has priority access to doses manufactured within the UK, any shortfall made up from outside the UK would not be on a priority basis. However, none of the contracts included penalties for late delivery.

All the contracts included indemnity cover to the companies by the UK government. By September 2021, the UK had secured access to 417 million doses from seven manufacturers[34], at an average price of approximately £10 per dose.

In addition to purchasing future vaccines, the taskforce also worked on the development of an industrial capacity to support vaccine production. By November 2020, it had committed £302 million in government funding in support of this aim, mostly to build or secure ever-ready vaccine production and fill and finish capacity.

44 None of the eight APAs provides explicitly for priority access to vaccines for the EU in the event of global demand exceeding supply. All EU contracts provide for a warranty from the company that they do not have any contracts conflicting with the

[32] UK Vaccine Taskforce 2020, Achievements and Future Strategy, December 2020.

[33] UK National Audit Office, "Investigation into preparations for potential COVID-19 vaccines", 16.12.2020.

[34] UK Department of Health and social care, press release, 28.4.2021.

EU contract. Three of the later contracts do state that the contractor must not enter into any agreements or commitments that would impede its ability to meet its obligations under the contract. Two of the contracts signed in 2021 include reinforced contractual clauses, along with penalties, to prioritise supplies to the EU from 2022 onward. These provisions improved the protection afforded to the EU's interests in securing vaccine supplies for the Member States.

Box 3

The US approach to vaccine procurement

As of 30 September 2021, the United States had committed at least $28.2 billion to purchase 1.7 billion vaccine doses from six vaccine manufacturers[35]. Most of the contracts the US concluded with manufacturers were flexible agreements with short award times and the possibility to negotiate specific terms and conditions.

The Department of Defence and the Department of Health and Human Services together called on staff with relevant experience and expertise (e.g. supply chain, drug development) to organise the US government's vaccine procurement. In addition, five of the six agreements provide for government officials being embedded in manufacturers' facilities. This gave the government insight into vaccine manufacturers' production capabilities and the challenges they faced[36].

During the COVID-19 pandemic, the US government frequently invoked the Defense Production Act (DPA) under which the government can conclude priority-rated contracts or placed orders that take precedence over any others if a contractor is unable to make all of the contracted deliveries on time. All six vaccine manufacturers benefited from priority ratings, which helped provide them with timely access to raw materials and supplies[37]. The US government can also use the DPA to prevent companies from exporting certain goods.

The Public Readiness and Emergency Preparedness Act gives manufacturers of COVID-19 vaccines immunity from legal liability for losses related to the administration or use of their vaccines (i.e. they cannot be sued for damages in court).

[35] US Government Accountability Office report, GAO-22-104453 of January 2022.

[36] US Government Accountability Office report, GAO-21-443 of April 2021.

[37] US Government Accountability Office report, GAO-21-387 of March 2021.

Manufacturing in the EU

45 The Commission strategy aimed at a sufficient production of vaccines in the EU for reasons of security of supply, but the structure of the global supply and production chains meant that the contracts allowed production steps to take place in non-EU locations. All 11 contracts include a clause on the location of vaccine production, although the earlier contracts have less strict requirements to manufacture in the EU. Six contracts allow the contractors to use facilities in the US, Switzerland, the UK or the EEA identified in the contract. Four contracts specify that the contractor needs to inform the Commission if it intends to use additional facilities located outside the EU. In four other cases, the contractor needs to obtain the Commission's prior consent to use facilities outside the EU, UK, EEA or Switzerland.

Liability and indemnification

46 According to the Commission, the JNT was under pressure from the pharmaceutical industry to follow the example of the US, which had released companies from their liability for COVID-19 vaccines[38] (see ***Box 3***). However, with the support of the steering board, the JNT set a red line for the negotiations, namely that the EU Product Liability Directive, the legal framework on liability for defective medicinal products, must be respected (see ***Box 1***).

47 Two contracts state that the indemnification clause may be re-discussed if additional doses are ordered or if vaccine doses are supplied during an extension of the contract. At a steering board meeting in July 2020, the Commission acknowledged that the indemnification clause currently in force should be limited in time and may not be necessary once a standard marketing authorisation has been granted. Our survey of steering board members confirms that many Member States share this view. Three-quarters of the respondents are of the opinion that the liability/indemnification regime currently provided for in the contracts should be amended once a vaccine receives a standard marketing authorisation, so that Member States carry less financial risk.

[38] US Health and Human Services Department, Declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures, 17.3.2020.

We did not receive any information on the preliminary negotiations for the EU's biggest contract

48 In mid-March 2021, the steering board agreed to plan a meeting with EU and national scientific advisors on the scientific aspects of the vaccine strategy for 2022. Such a meeting never took place. During March 2021, the President of the Commission conducted preliminary negotiations for a contract with Pfizer/BioNTech. This was the only contract for which the JNT was not involved in this stage of negotiations, contrary to the Commission decision on procuring COVID-19 vaccines[39]. On 9 April 2021, the Commission presented to the steering board the conditions negotiated between the President of the Commission and Pfizer/BioNTech, and the steering board agreed to launch a call for tender. The contract was signed on 19 May 2021 (see ***Table 1***) and covers 900 million vaccine doses to be delivered in 2022 and 2023, with the option of ordering another 900 million doses. It is the biggest COVID-19 vaccine contract signed by the Commission and will dominate the EU's vaccine portfolio until the end of 2023.

49 We asked the Commission to provide us with information on the preliminary negotiations for this agreement (scientific experts consulted and advice received, timing of the talks, records of the discussions, and details of the agreed terms and conditions). However, none was forthcoming.

50 Furthermore, the European Ombudsman opened a case on 16 September 2021 on the separate matter of the European Commission's refusal to grant public access to text messages exchanged between the Commission President and the CEO of Pfizer at the time of the preliminary negotiations. Her report of 26 January 2022 finds that the way the Commission dealt with this request constituted maladministration. The report recommends[40] that the Commission "search again for relevant text messages" and "assess whether public access can be granted to them in line with Regulation 1049/2001".

[39] Commission Decision, C(2020) 4192 final.

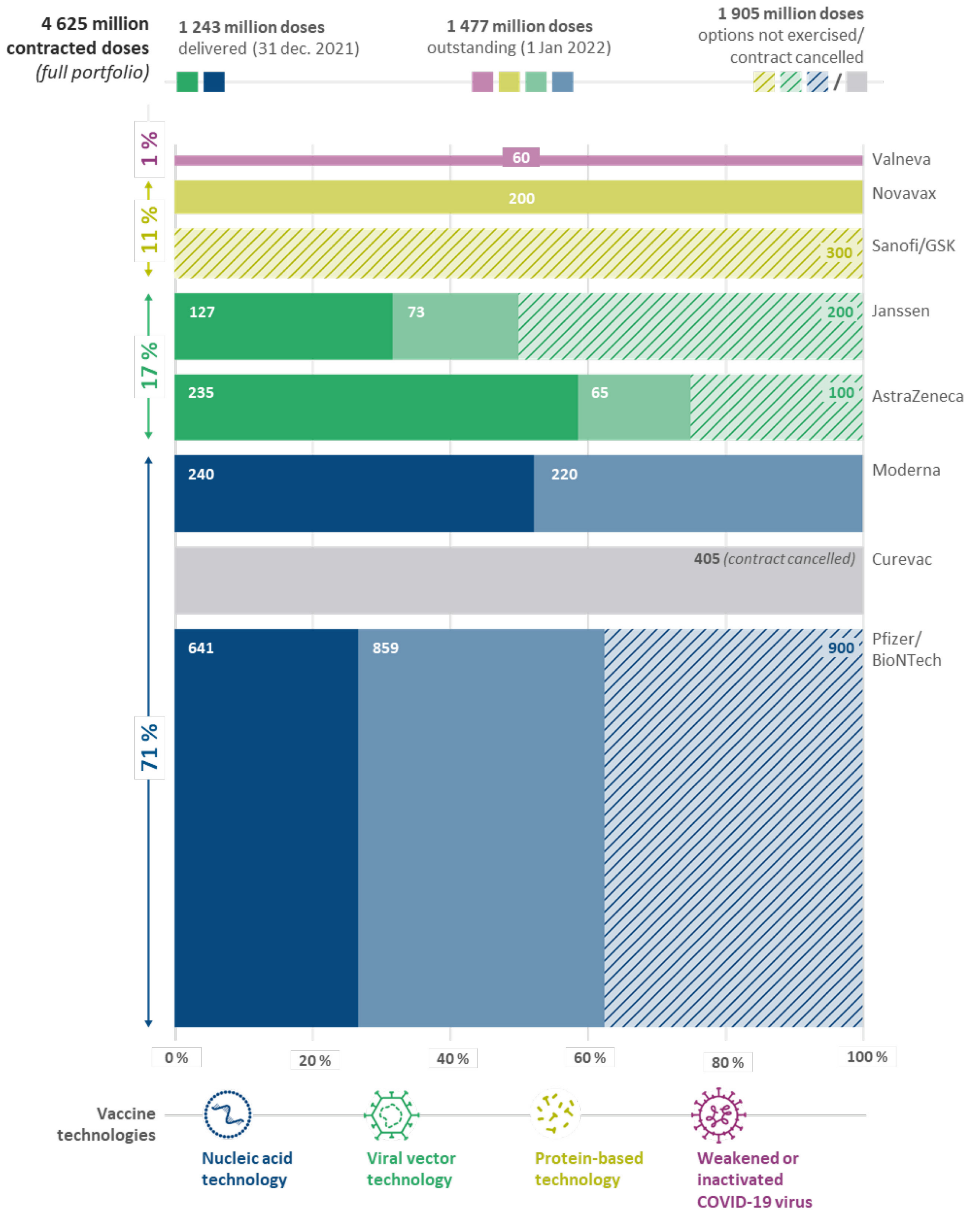
[40] European Ombudsman recommendation, case 1316/2021/MIG, 26.1.2022.

The Commission achieved a diversified vaccine portfolio, but the EU is mainly dependent on one supplier for 2022-2023

51 The steering board considered it important to have a diversified portfolio of vaccines based on different technologies. Vaccine development is a complex process and most vaccines in early development fail. Investing in a wide range of vaccine technologies is a means of spreading risk. The UK and the US have followed a similar approach. The EU included eight vaccine candidates in its portfolio, covering four different vaccine technologies (see ***Annex***).

52 By 31 December 2021, five vaccines had been authorised for use in the EU, and four manufacturers covering two of the main vaccine technologies had delivered a total of 952 million doses (***Figure 8***). The majority of vaccine doses delivered use mRNA technology. The share of mRNA doses administered is still higher as many of the doses donated to third countries up to January 2022 are from AstraZeneca and Janssen, both viral vector technology.

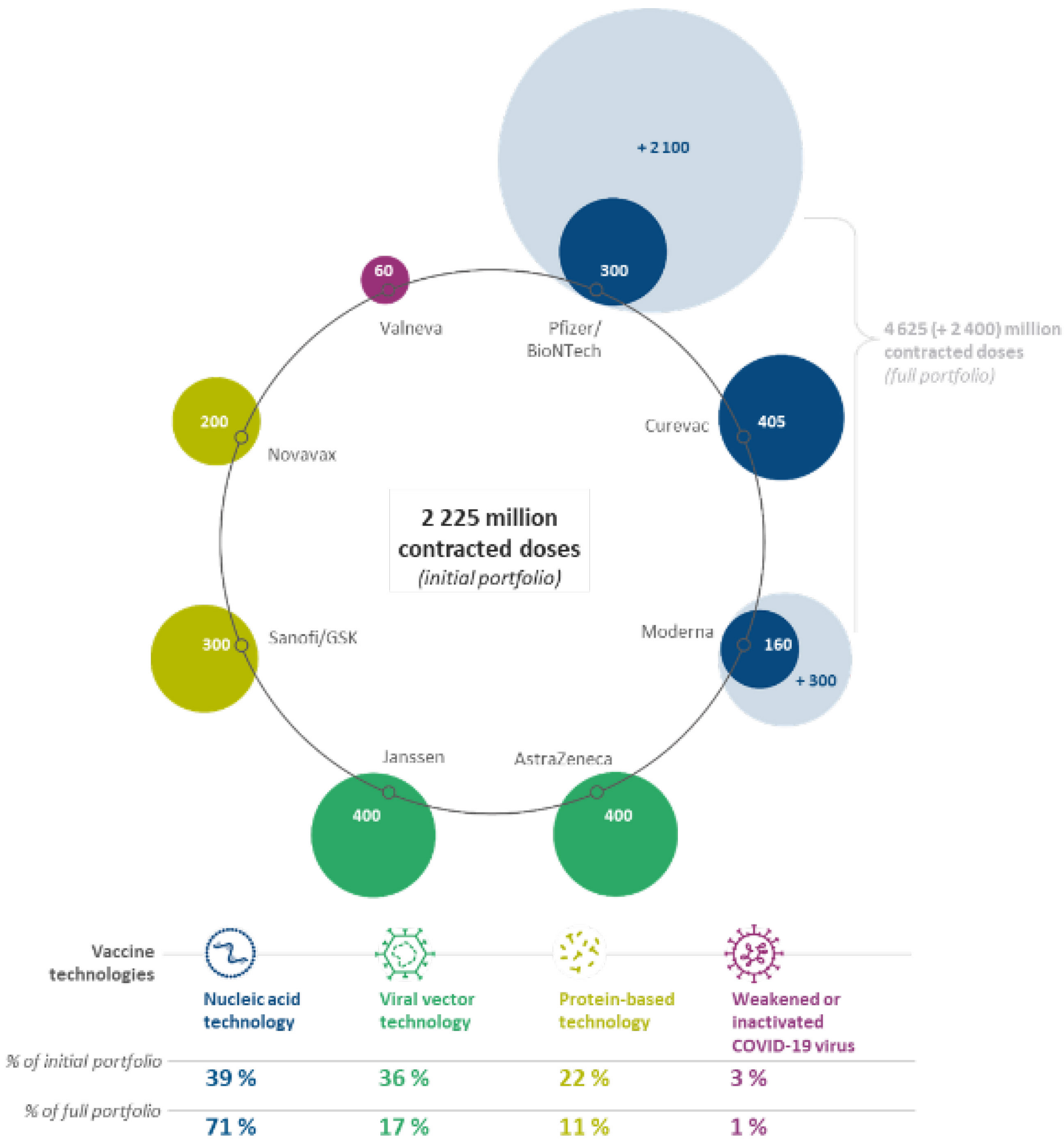
Figure 8 – Proportion of contracted doses versus doses delivered by company, and outstanding quantities to be delivered



Source: ECA based on contracts and ECDC data.

53 The vaccine portfolio has evolved and relies heavily on mRNA technology-based vaccines up to the end of 2023 (see ***Figure 9***), due mainly to the contract of 900 million doses (with an optional additional 900 million doses) with Pfizer/BioNTech. The Commission informed us that the decision to rely on this company was motivated by its ability to reliably supply the EU.

Figure 9 – Initial and full EU vaccine portfolio



Source: Advance Purchase Agreements.

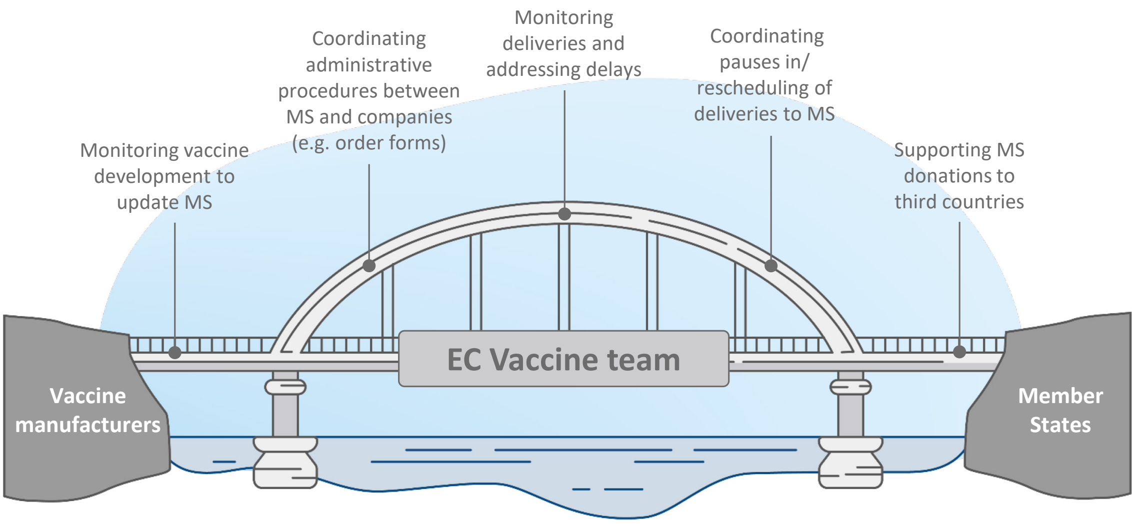
The Commission supported contract implementation but had limited leverage to overcome supply challenges

54 Once the contracts were concluded, the Commission followed up their implementation. We assessed whether the Commission ensured the timely implementation of the contracts and addressed any issues impacting the supply of vaccines.

The Commission acted as a bridge between companies and Member States for contract implementation

55 The Commission bought doses on behalf of the Member States through the contracts. The Member States are therefore the manufacturers' counterparties as regards payment, order forms, receipt of doses, etc. Nevertheless, the Commission took some actions to support the implementation of the contracts (see ***Figure 10***).

Figure 10 – Contract implementation: the Commission's main activities



Source: ECA.

56 As the volume of doses delivered to Member States has increased, the Commission has coordinated vaccine donations aiming to fulfil the EU's pledge to donate 500 million doses to third countries. It has also coordinated the postponement or acceleration of deliveries to some Member States to avoid oversupply or shortages. These activities, while not all formally part of the agreement between the Commission and Member States, supported the execution of the contracts and delivery of doses.

The EU faced vaccine delivery problems in the first half of 2021

57 The supply shortfalls from AstraZeneca and Janssen in 2021 highlight the challenges the EU faced addressing production and supply disruptions. AstraZeneca and Janssen each delivered a third of contractually agreed volumes by the end of June 2021[41]. Pfizer/BioNTech and Moderna also experienced disruptions to their supply to the EU that were either temporary (Pfizer/BioNTech) or in the second half of 2021 and therefore had less impact on overall supply (Moderna).

58 Most of the contracts did not include specific provisions to prioritise deliveries to the Member States. This left the Commission with few options other than taking manufacturers to court for failing to make "best reasonable efforts" to deliver vaccines, or for breaching the warranty on the absence of conflicting contracts. The Commission did take AstraZeneca to court (see ***Box 4***) but not Janssen, which communicated to the Commission the challenges it faced and efforts it made trying to ramp-up production once its vaccine received market approval in March 2021[42]. Deliveries from both companies remained well below expected volumes in 2021 despite Commission actions to support or enforce delivery timetables.

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[41] ECDC vaccine tracker.

[42] Johnson & Johnson statement, 31.3.2021.

Box 4

The Commission took AstraZeneca to court for breach of contract

On 4 December 2020, AstraZeneca informed the Commission that it would not be able to deliver the number of doses agreed in the contract in the first quarter of 2021.

In the first quarter of 2021, deliveries were significantly lower than agreed (30 million doses instead of 120 million foreseen in the contract), with AstraZeneca submitting explanations the Commission considered incomplete and invalid. The contract with AstraZeneca did not explicitly provide remedies for such a situation. In March 2021, the Commission therefore launched a legal case against AstraZeneca under Belgian law for late delivery, and another in April seeking faster delivery and financial compensation.

In June 2021, the Brussels Court of First Instance ruled that AstraZeneca was in intentional breach of the contract in that it had chosen not to use its Halix (NL) and Oxford (UK) manufacturing sites to supply the EU, thereby giving priority to supplying the UK. The Court ordered AstraZeneca to deliver 50 million doses of vaccine by 27 September 2021, in accordance with a binding schedule, and set a penalty of €10 per dose not delivered by that date.

On 3 September 2021, the EU and AstraZeneca agreed a new delivery schedule for the period up to March 2022 for the outstanding doses, with more binding delivery obligations on AstraZeneca. This agreement also led the Commission to withdraw all requests for compensation.

59 While supplementary Pfizer/BioNTech deliveries enabled the EU to overcome the shortfall in deliveries from AstraZeneca and Janssen, these delays were a factor impacting the scale and speed of vaccinations in the first half of 2021, when the EU was slower to vaccinate its population than the UK and the US (see ***Figure 4***). The US in particular had legal recourse to support security of supply (see ***Box 3***).

60 The EU put in place an export authorisation scheme for COVID-19 vaccines on 30 January 2021[43], which ran until the end of December 2021[44]. This scheme allowed the Commission and Member States to track vaccine exports and block them if for example a vaccine manufacturer did not respect its delivery obligations. One shipment

[43] Commission Implementing Regulation 2021/111.

[44] Commission Implementing Regulation 2021/1728.

was blocked using this scheme[45]. Blocking vaccine exports is an instrument of last resort for the Commission, which has stressed its commitment to exporting vaccines to help fight the pandemic[46].

The Commission only created a task force to support manufacturing and supply chains in February 2021

61 In February 2021, the OECD cautioned that there is "a high degree of trade interdependence in the goods needed to produce, distribute and administer vaccines", and "existing evidence on production capacity is scarce"[47]. The President of the Commission acknowledged that producing a new vaccine is a complex process and admitted that "overall we have underestimated the difficulties inherent in mass production"[48].

62 The Commission's Task Force for Industrial Scale-up of COVID-19 vaccines (TFIS) was set up in February 2021, eight months after the steering board for vaccine procurement and JNT had started work. It was also nine months after the Commission had committed to exploring supporting the scaling up of vaccine production[49] and eight months after the Commission had assessed the likelihood of other economies imposing export restrictions on vaccines. The TFIS was not specifically created to support ongoing negotiations but rather as part of the preparations for the launch of Health Emergency Preparedness and Response Authority (HERA)[50], to help respond to production issues blocking the scaleup of COVID-19 vaccine production. The TFIS's main activities include:

- identifying and removing vaccine production bottlenecks in the EU;

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[45] Statement by President von der Leyen at the joint press conference with President Michel, 25.3.2021.

[46] Speech by President von der Leyen at the launch of the Belgian Biopharma Platform, 26.10.2021.

[47] OECD, "Using trade to fight COVID-19: Manufacturing and distributing vaccines", 10.2.2021.

[48] Speech by President von der Leyen at the European Parliament Plenary on the state of play of the EU's COVID-19 Vaccination Strategy, 10.2.2021.

[49] Joint European Roadmap towards lifting COVID-19 containment measures, 17.4.2020.

[50] Commission Communication on the HERA Incubator, COM(2021) 78.

- mapping EU vaccine production capacities throughout the supply chain;
- facilitating partnerships through matchmaking events for vaccine and therapeutics production;
- ensuring sufficient long-term manufacturing capacity in Europe;
- supporting global vaccine access and vaccine sharing efforts[51].

63 The TFIS mapped and monitored COVID-19 vaccine production in the EU. It did this mainly through meetings with the contract signatories, suppliers to these vaccine manufacturers and Member State authorities. The TFIS carried out more detailed research, including site visits, on four vaccine manufacturers and their subcontractors to ascertain their production capacities and supply networks and assess potential risks to their capacity to deliver. In all but one case, these assessments were completed just days before the contracts were signed, and thus too late to influence contract negotiations.

64 By comparison, both the UK and the US anticipated manufacturing and supply problems earlier in the process, either by funding the development of industrial capacity or by having officials actively monitoring and supporting companies production efforts (see ***Box 2*** and ***Box 3***).

65 The proposed Council Regulation on an emergency framework for medical countermeasures[52] provides for the Commission to create inventories of relevant production facilities (including their supply chains) when the relevant measure the emergency framework is activated. HERA will prepare for the eventual activation of this provision through continuous monitoring and mapping of relevant supply chains and production capacities[53].

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[51] European Commission website: "Task Force for Industrial Scale-up of COVID-19 vaccines", accessed 1.4.2022.

[52] Proposal for a Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, COM/2021/577 final.

[53] Commission Communication, "Introducing HERA", COM(2021) 576.

The Commission helped resolve bottlenecks although the size of its impact on the ramp up of production is unclear

66 The Commission monitored and mapped EU-based vaccine production to identify where the vaccine production and supply chain was experiencing shortages or bottlenecks, or risked doing so. It did this in order to help address such problems and ramp up production. According to the Commission, the most critical shortages facing vaccine manufacturers in the EU in the first half of 2021 were of bioreactor bags, filters and tubes.

67 The TFIS supported vaccine manufacturers facing such shortages, as well as those looking for spare production or fill and finish capacity, by acting as a facilitator, establishing contacts between different companies and between companies and the relevant Member State authorities. It also held regular meetings with its US counterpart to help mitigate shortages in the EU linked to US government "priority orders" of vaccine-related inputs (see ***Box 3***). These contacts were formalised in September 2021 through the creation of the EU-US joint COVID-19 Manufacturing and Supply Chain Taskforce[54].

68 The TFIS was able to play a facilitating and supporting role in this area but the size of the impact on its stated aim to "ramp-up production capacity for vaccines in the EU"[55] is unclear. Increases in production capacity resulted to a significant extent from commercial decisions taken by manufacturers in response to contracts signed with the Commission and other customers, often before the TFIS had been set up.

The Commission has not evaluated or benchmarked its procurement of COVID-19 vaccines

69 The EU's COVID-19 vaccine procurement efforts secured, from different manufacturers, sufficient doses both to vaccinate all EU adult citizens and to make donations to third countries by the end of 2021. The proposed Council Regulation on

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[54] US-Commission joint statement: Launch of the joint COVID-19 Manufacturing and Supply Chain Taskforce, 22.9.2021.

[55] European Commission website: "EU vaccine strategy", accessed 4.1.2022.

an emergency framework for medical countermeasures[56] provides for the possibility to activate a similar procurement structure to that used in response to COVID-19 in case of future health emergencies.

70 The Council[57] and Commission[58] have each published a "lessons learned" document on COVID-19 and public health. Neither examined the performance of the vaccine procurement process, beyond its overall outcome, in order to identify areas for improvement. This is despite the Council inviting the Commission to evaluate and report on, within the first half of 2021, "the procurement of medical countermeasures and the Emergency Support Instrument with respect to, *inter alia*, governance structure, transparency and information exchange between the Commission and the Member States"[59]. The Commission's proposal for the Council Regulation on an emergency framework for medical countermeasures was not supported by a dedicated impact assessments or public consultation. The proposed regulation on an emergency framework for medical countermeasures mandates a review of its provisions by 2024.

71 The Commission did not consider in detail the operation and structure of EU vaccine procurement to understand what enabled it to secure sufficient doses and what were the risks to that outcome. It has also not benchmarked this process against other vaccine procurement systems to identify best practices. The Commission told us that it has not analysed the publicly available information on the vaccine manufacturers' contractual clauses obtained by third countries to identify examples of what the EU could aim for in future negotiations to improve the security of vaccines supply.

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[56] Proposal for a Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, COM/2021/577 final.

[57] Council conclusions on COVID-19 lessons learnt in health, 18.12.2020.

[58] Commission Communication, "Drawing the early lessons from the COVID-19 pandemic", COM/2021/380.

Conclusions and recommendations

72 We examined the Commission's preparations for the procurement of COVID-19 vaccines as well as the conduct of the negotiations and the extent to which the EU's negotiators were able to secure the EU's procurement objectives in the contracts it signed with vaccine manufacturers. We also examined what remedies the EU could use when faced with supply disruptions and how the Commission helped support the production of vaccines for the EU.

73 We conclude that by signing contracts with a number of different manufacturers covering different technologies in order to spread and reduce the risk of failed vaccine development, the EU managed to procure COVID-19 vaccines it needed.

74 We found that the EU's preparations for the procurement of COVID 19 vaccines were mostly effective. The EU identified vaccines as a key element in the fight against COVID-19 early on in the pandemic (see paragraph ***18***) and took steps to create an ad hoc and tailor-made procurement system to secure vaccines for EU citizens. However, the EU started this procurement process later than the UK and the US (see ***Figure 4***).

75 The EU had to act ahead of clear scientific data on vaccine candidates' safety and efficacy (see paragraph ***30***), and therefore chose to back a range of candidates in its initial portfolio. The initially diversified portfolio of vaccines is dominated by the Pfizer/BioNTech vaccine for 2022-2023 (see ***Figure 8***), which the Commission states is necessary for reasons of security of supply. The Commission produced its vaccine strategy in the early stages of the pandemic, at a time when there were no COVID-19 vaccines on the market (see paragraph ***24***).

76 The EU's negotiators were better able to secure the EU's procurement objectives in the later contracts it signed with vaccine manufacturers. The terms of the contracts evolved over time and those signed in 2021 have stronger provisions on key issues such as delivery schedules and production location than those signed in 2020. EU negotiators took a flexible approach to negotiations with vaccine manufacturers, imposing only one negotiating red line: adherence to the Product Liability Directive (see paragraph ***46***). The liability and indemnification clauses have remained the same: Member States have taken over some of the financial risk (i.e. compensation payments and legal costs) linked to vaccine administration from the manufacturers. This reflects the unique circumstances at the time these clauses were agreed. The Commission and

ten of the 14 Member States that responded to our survey wish to see a more standard liability regime when the standard marketing authorisation has been granted.

77 We found that the Commission had limited leverage to overcome supply challenges. The Commission acted as a bridge between companies and Member States for contract implementation (see paragraph ***56***) but it did not fully analyse the production and supply chain challenges of vaccine production until after signing most of the contracts (see paragraph ***63***) and most contracts did not include specific provisions to address supply disruptions (see paragraph ***58***). The Commission could, and in one case did, take manufacturers to court (see ***Box 4***). The Commission only set up a task force to support manufacturing and supply chains in February 2021 (see paragraph ***62***) and while it did help resolve bottlenecks, its impact on the ramp-up of vaccine production was unclear(see paragraph ***67***).

78 A new procurement system was rapidly set up and delivered a diversified portfolio of vaccine candidates for the EU. The Commission proposed to continue the procurement approach set up for COVID-19 for future health crises, but neither the Commission's nor the Council's "lessons learned" reports on the COVID-19 pandemic examined the performance of the vaccine procurement process, beyond its overall outcome. The Commission has not studied third country procurement systems to identify good practices (see paragraph ***71***).

Recommendation 1 – Create pandemic procurement guidelines on the basis of lessons learnt

Once the Emergency Framework Regulation and the revised Financial Regulation have been adopted, after consulting Member State authorities and relevant stakeholders, and benchmarking with other procurement systems to identify good practices, the Commission should produce pandemic procurement guidelines and/or lessons learnt for future negotiating teams.

Target implementation date: one year from of the adoption of the two legal bases

79 The EU is putting in place a range of new pandemic preparedness and response measures following the outbreak of the COVID-19 pandemic. It is as a result taking on a greater role in preparing for and responding to pandemics, notably in the field of procurement (see paragraph ***69***). The Commission did not evaluate and report on the procurement of medical countermeasures and the use of the Emergency Support Instrument, despite having been invited by the Council to do so (see paragraph ***71***).

80 The EU's new competences and activities were not determined on the basis of an ex-ante impact assessment (see paragraph *70*). Issues in the EU's procurement process such as identifying which skills are needed in the EU's negotiating team (see paragraph *26*) or how the EU can best contribute to solving supply chain and production issues remain to be addressed (see paragraph *68*).

81 Despite the WHO considering pandemic planning exercises to be an integral part of preparedness and despite the Commission supporting preparedness and response projects at EU and Member State level since 2003 (see paragraph *22*), the Commission is not currently planning to test its new competences for procurement of medical countermeasures through exercises and simulations to identify and address areas for improvement.

Recommendation 2 – Stress-test the EU's medical countermeasures procurement approach

The Commission should, in order to be in line with best practices and contribute to the review of the Council Regulation on an emergency framework for medical countermeasures:

(a) carry out a risk assessment of the EU's procurement approach and propose appropriate measures;

(b) run exercises to test all parts of its updated pandemic procurement framework, including information and intelligence gathering, to identify any weaknesses and areas for improvement and publish the results.

Target implementation date: Q2 2024

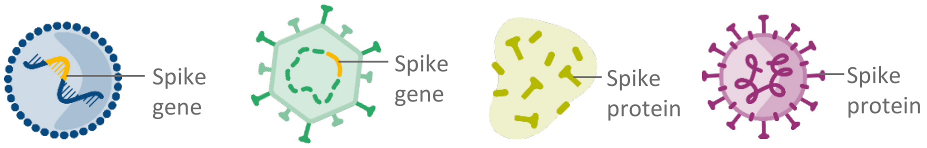
This report was adopted by Chamber I, headed by Ms Joëlle Elvinger, Member of the Court of Auditors, in Luxembourg at its meeting of 6 July 2022.

For the Court of Auditors

Klaus-Heiner Lehne
President

Annex

Vaccine technologies in the EU COVID-19 vaccine portfolio



Vaccine technologies in EU portfolio	**Nucleic acid** *(mRNA)*	**Viral vector** *(replicating or non-replicating)*	**Protein-based**	**Virus** *(weakened or inactivated)*
Description	The vaccine contains a molecule called messenger RNA (mRNA) with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19.	The vaccine is made up of another virus (e.g. of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2.	The vaccine contains a version of a protein found on the surface of SARS-CoV-2 (the spike protein), which has been produced in the laboratory.	The vaccine contains the COVID-19 virus itself, in a weakened or inactivated form.
Existing vaccines using this technology	-	Recent vaccine against ebola	Vaccines against seasonal influenza, human papillomavirus (HPV) and hepatitis B (HBV)	Vaccines against measles, mumps, rubella and polio
Vaccine candidates in EU portfolio	Moderna Pfizer/BioNTech Curevac	Janssen AstraZeneca	Novavax Sanofi Pasteur	Valneva
Authorised for use in the EU?	**Yes:** Spikevax (Moderna) Comirnaty (Pfizer/BioNTech) **No:** Curevac withdrew its vaccine CVnCoV from the autorisation process in October 2021.	**Yes:** COVID-19 Vaccine Janssen (Janssen) Vaxzevria (AstraZeneca)	**Yes:** Nuvaxovid (Novavax) **No:** Vidprevtyn (Sanofi Pasteur) under rolling review	**No:** VLA2001 (Valneva) under rolling review

Source: ECA based on GAO and EMA data.

Acronyms and abbreviations

APA: Advance purchase agreement

EEA: European Economic Area

ECDC: European Centre for Disease Prevention and Control

ESI: Emergency Support Instrument

EMA: European Medicines Agency

HERA: European Health Emergency Preparedness and Response Authority

IFPMA: International Federation of Pharmaceutical Manufacturers & Associations

IVA: Inclusive Vaccine Alliance

JNT: joint negotiation team

mRNA: Messenger RNA

OECD: Organisation for Economic Co-operation and Development

PA: Purchase agreement

TFIS: Task Force for Industrial Scale-up of COVID-19 vaccines

WHO: World Health Organisation

Glossary

Advance Purchase Agreements: Agreement concluded with a supplier to purchase a specified quantity of a product in the future.

Bioreactor bags: A single-use bioreactor is a plastic bag made of a multilayered polymer film.

Conditional marketing authorisation: Emergency authorisation to make a medicine available even though the requirement for comprehensive clinical data has not yet been met.

Containment measure: Action or policy to contain the spread or transmission of the SARS-CoV-2 virus in areas or communities where it has already taken hold. These measures include lockdowns, quarantine, isolation, and cordon sanitaire.

Emergency Support Instrument: Financial instrument directly managed by the Commission that allows it to provide support within the EU in case of disasters.

European Medicines Agency: EU agency that provides independent recommendations on medicines for human and veterinary use, based on a comprehensive scientific evaluation of data. The Agency's evaluations of marketing-authorisation applications provide the basis for the authorisation of medicines in Europe.

European Health Emergency Preparedness and Response Authority: A Commission service that has been set up to improve preparedness and response to serious cross-border threats in the area of medical countermeasures.

Financial Regulation: The rules governing how the EU budget is set and used, and the associated processes such as internal control, reporting, audit and discharge.

Operation Warp Speed: U.S. initiative to develop and deliver 300 million doses of a COVID-19 vaccine by January 2021.

Standard Marketing authorisation: Marketing authorisation granted by the European Commission after evaluation by the EMA of complete data confirming that the medicine's benefits continue to outweigh its risks. Initially valid for five years, it can then be renewed indefinitely.

Task Force for Industrial Scale-up of COVID-19 Vaccines: Team set up within DG GROW with the involvement of several Commission services to support the increase in COVID-19 vaccine production capacity.

Vaccine candidate: Potential vaccine under development at the time of negotiations between the EU and vaccine manufacturer.

Replies of the Commission

https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=61899

Timeline

https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=61899

Audit team

The ECA's special reports set out the results of its audits of EU policies and programmes, or of management-related topics from specific budgetary areas. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This performance audit was carried out by Audit Chamber I Sustainable use of natural resources, headed by ECA Member Joëlle Elvinger. The audit was led by ECA Member Joëlle Elvinger, supported by Ildikó Preiss, Head of Private Office and Paolo Pesce, Private Office Attaché; Nicholas Edwards, Head of Task; Paul Stafford, Principal Manager; Els Brems, Auditor; Aleksandra Melesko, Legal Support and Marika Meisenzahl, Auditor and graphic design. Judita Frangež provided secretarial support.



From left to right: Aleksandra Melesko, Paul Stafford, Joëlle Elvinger, Nicholas Edwards, Ildikó Preiss, Marika Meisenzahl and Paolo Pesce.

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The EU launched its vaccine procurement strategy in June 2020. By the end of 2021, it had signed €71 billion worth of contracts securing up to 4.6 billion doses. We conclude that the EU secured a diversified vaccine portfolio for Member States, though it started procurement later than the UK and the US. The contracts signed in 2021 have stronger provisions on key issues than those signed in 2020. We found that the Commission had limited leverage to overcome supply challenges and the size of its impact on the ramp-up of vaccine production was unclear. Our recommendations focus on the need to draw lessons learnt and run exercises to test the EU's updated pandemic preparedness framework.

ECA special report pursuant to Article 287(4), second subparagraph, TFEU.

EUROPEAN COURT OF AUDITORS

Publications Office of the European Union

EUROPEAN COURT OF AUDITORS
12, rue Alcide De Gasperi
1615 Luxembourg
LUXEMBOURG

Tel. +352 4398-1

Enquiries: eca.europa.eu/en/Pages/ContactForm.aspx
Website: eca.europa.eu
Twitter: @EUAuditors